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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/765,287	09/12/1997	CAMILLE LOCHT	960-25	5876

7590 12/18/2001

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EXAMINER

SHAHNAN-SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/765,287

Applicant(s)

LOCHT ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2001 and 13 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18-22, 27-30, 34, 35 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-15, 18-22, 27-30, 34, 35 and 38-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

1. The Examiner of U.S. Patent application SN 08/765,287 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Shahnan-Shah, Technology Center 1600, Art Unit 1645.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2001, paper # 24 has been entered.

Applicants' Amendments

3. Acknowledgement is made of Applicants' amendments F filed 1/26/2001 paper number 22, which has been entered.

Status of the Claims

4. Claims 16-17 have been canceled; new claims 40-41 have been added. Claims 1-15, 18-22, 27-30, 34-35 and 38-41 are pending and under consideration.

Prior Citations of Title 35 Sections

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

6. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or form PTO-1449 have been submitted with this office action.

Rejection (s) Moot

7. The rejection of claims 16 and 17 made on page 3 and 4 of the office action mailed 9/26/2000 (paper no. 21) under 35 U.S.C. 103 (a) is moot in light of applicants' cancellation of the claims.

Rejection (s) Maintained

Claim Rejections - 35 USC § 103

8. The rejection of claims 1-15, 18-22, 27- 30 and 39 made on page 3, 4 and 5 of the office action mailed 9/26/2000 (paper no. 21) under 35 U.S.C. 103 (a) over Loosmore et al. (EP 453216) in view of Menozzi et al. (FEMS Microbiology Letters, 78:59-64, 1991) is maintained for reasons set forth therein and those that are set forth here below.

Applicants contended that the rejection is traversed. Applicants argue that there is nothing in Loosmore et al. that describes or suggests the construction of a recombinant DNA encoding a fusion protein comprising an amino acid sequence from Fha fused to an amino acid sequence from a protein distinct from Fha. Applicants further argue that Menozzi et al. does not remedy the deficiencies of the primary reference.

Applicants' arguments have been carefully considered, but they are not persuasive. Examiner respectfully is drawing applicants' attention to columns 3 and 4 of Loosmore et al. patent application specially column 4 lines 20- 58. They teach fusion protein comprising an amino acid sequence from Fha fused to an amino acid sequence from a protein distinct from Fha. They teach Fhap/TOX, Fhap/PRN and TOXp/Fha. They also teach a recombinant strain with

kinetics and yields comparable to the wild type strains. With regard to the reference of Menozzi et al. applicants acknowledge that the reference teaches the Fha-heparin interactions, but contend that it does not teach a fusion protein construct comprising a Fha moiety.

The applicants' argument has been carefully considered, but it is not persuasive. The reference of Menozzi et al. has been applied to indicate the art-known fact that the Fha, for example of Loosemore et al. contains the heparine interaction site. That the hybrid gene of Loosemore et al. expresses Fha that contains the heparine interaction site is implicit in the disclosure of Loosemore et al. in light of what is well known in the art, as taught by Menozzi et al. Therefore the rejection based on the above references is proper under 35 U.S.C. 103 (a).

9. The rejection of claims 34 and 35 made on pages 6 and 7 of the office action mailed 3/16/2000 (paper no. 19) under 35 U.S.C. 103 (a) over Loosmore et al. (EP 453216) in view of Menozzi et al. (FEMS Microbiology Letters, 78:59-64, 1991) and Lochter et al. is maintained for reasons set forth in paragraph 11, page 5 of the office action mailed 9/26/2000 (paper no. 21).

New Rejections

Claim Rejections - 35 USC § 102(e)

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 40-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Relman et al. (US Patent 6,036, 960) prior made of record in office action mailed 9/26/2000.

Claims 40-41 are drawn to the host cells belonging to a bacterial species other than *Bordetella*.

Relman et al. disclose host organisms or stains from pathogens other than *Bordetella*. They disclose other organisms such as *E. coli*, *Salmonella*, *Yersinia* or *Pseudomonas* (see column 4, lines 44-48) expressing a fusion protein or hybrid protein comprising a part of the filamentous haemagglutinin or Fha and a part of a protein heterologous to Fha. They disclose seven portions of the Fha B open reading frame were each cloned into the expression vector (see column 9).

Relman et al. disclose that nucleic acid and protein compositions are provided from *B. pertussis*, which may find use in diagnosis and treatment of disease. Particularly they disclose that an open reading frame encoding filamentous hemagglutinin precursors provided, with the intact protein for the filamentous hemagglutinin portion thereof can be expressed in a wide variety of hosts including *E. coli*, for use in the production of antibodies, for immunodiagnosis or therapy, or as vaccine for prophylactic purposes. (see abstract and claims).

Conclusion

11. Claims 1-15, 18-22, 27-30, 34-35 and 38-41 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnian-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 12/16/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645


MARK NAVARRO
PRIMARY EXAMINER